

**Supplementary table A: Definitions and measures of primary and secondary outcomes**

Outcome	Definition	Measurement
Surgical site infection	An infection that occurs within 30 days after surgery in the part of the body where the surgery took place, or within 90 days if prosthetic material is implanted at surgery <sup>1</sup> .	0=No, 1=Yes
Superficial infection	<p>Involves only skin and subcutaneous tissue of the incision; AND patient has at least one of the following<sup>1</sup>:</p> <ul style="list-style-type: none"> <li>• a) Purulent drainage from the superficial incision,</li> <li>• b) Organisms isolated from an aseptically- obtained culture from the superficial incision or subcutaneous tissue,</li> <li>• c) Superficial incision that is deliberately opened by a surgeon, attending physician, or other designee and is culture-positive or not cultured; and patient has at least one of the following signs or symptoms: pain or tenderness; localized swelling; erythema; or heat. A culture-negative finding does not meet this criterion,</li> <li>• d) Diagnosis of a superficial incisional surgical site infection by the surgeon or attending physician or other designee</li> </ul>	0=No, 1=Yes
Deep incision infection	<p>Involves deep soft tissues of the incision (eg, fascial and muscle layers; AND patient has at least one of the following<sup>1</sup>:</p> <ul style="list-style-type: none"> <li>• a) Purulent drainage from the deep incision,</li> <li>• b) A deep incision that spontaneously dehisces, or is deliberately opened or aspirated by a surgeon, attending physician, or other designee and is culture-positive or not cultured; and patient has at least one of the following signs or symptoms: fever (&gt;38°C), localized pain, or tenderness. A culture negative finding does not meet this criterion,</li> <li>• c) An abscess or other evidence of infection that is detected on gross anatomical or histopathologic exam, or imaging test</li> </ul>	0=No, 1=Yes
Organ/Space infection	<p>The infection appears to be related to the operation and the infection involves any part of the anatomy (organs or spaces), other than the incision, which was opened or manipulated during an operation and at least one of the following<sup>1</sup>:</p> <ul style="list-style-type: none"> <li>• a) Purulent drainage from a drain placed in the organ/space</li> </ul>	0=No, 1=Yes

	<ul style="list-style-type: none"> <li>• b) Organisms isolated from an aseptically obtained culture of the organ/space</li> <li>• c) An abscess or any other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination</li> <li>• d) Diagnosis of an organ/space surgical site infection by a surgeon or attending physician</li> <li>• e) Endometritis, defined as maternal temperature &gt;38.0°C on two occasions over a four hour period, or any temperature &gt;39.0°C over a period of &gt;12 hours after delivery with associated uterine tenderness, was considered organ/space surgical site infection</li> </ul>	
Bleeding	Excessive wound bleeding postoperatively which can be identified by strikethrough on dressing <sup>2</sup> .	0=No, 1=Yes
Dehiscence	A surgical complication in which a wound splitting or rupture along surgical suture necessitating intervention <sup>3</sup> .	0=No, 1=Yes
Haematoma	Collection of bloody fluid in the subcutaneous tissue due to failure of primary haemostasis or a bleeding diathesis <sup>4</sup> .	0=No, 1=Yes
Seroma	Wound seroma is defined as a serous fluid that accumulates in the subcutaneous tissue <sup>4</sup> .	0=No, 1=Yes
Hospital length of stay	The duration of a single episode of hospitalisation calculated from admission day to the day patient was discharged.	Continuous
Readmission	A hospital readmission occurs when the patient has been discharged from hospital and is admitted again within 30 days <sup>5</sup> .	0=No, 1=Yes
Pain	Defined as the presence of postoperative pain at or near the surgical wound area.	0=No, 1=Yes
Reoperations	Returned to surgery within 30 days of having CS procedure because of surgical wound complications.	0=No, 1=Yes
Dressing related adverse events -blistering	Occurs when the epidermis is separated from the dermis and results from continued friction on the skin. This may be noted around dressing margins <sup>6</sup> .	0=No, 1=Yes
Dressing related adverse events - itchiness or rash	Itchiness or rash that is caused by tape adhesive around the surgical wound area.	0=No, 1=Yes
Serious adverse events-death	Any untoward medical occurrence that results in death (maternal or infant).	0=No, 1=Yes
Serious adverse events-ICU admission	Any untoward medical occurrence that requires admission to ICU.	0=No, 1=Yes

Serious adverse events-life threatening condition	Any untoward medical occurrence that is life-threatening; requires inpatient hospitalisation or prolongation of existing hospitalisation.	0=No, 1=Yes
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## References

1. Mangram AJ, Horan TC, Michele L. Pearson, et al. Guideline for prevention of surgical site infection. Infect Control Hosp Epidemiol: The University of Chicago Press on behalf of The Society for Healthcare Epidemiology of America, 1999:250—80.
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**Supplementary table B: Multiple logistic regression analysis for potential risk factors for SSI identified in the literature**

Predictor variable	Coefficient b	OR (95% CI)	Wald $\chi^2$	p-value
Group (Reference: Control)	-.34	0.71 (0.52 to 0.98)	4.31	0.04
BMI				
30.0 to 34.9	ref	ref	7.19	0.07
35.0 to 39.9	-.01	0.99 (0.66 to 1.5)	.001	0.97
40 to 49.9	.46	1.58 (1.08 to 2.31)	5.46	0.02
>50	.47	1.60 (0.76 to 3.36)	1.53	0.22
Parity				
Parity 0	ref	ref	3.46	0.33
Parity 1	0.25	1.28 (0.80 to 2.06)	1.07	0.30
Parity 2	0.49	1.63 (0.96 to 2.74)	3.32	0.07
Parity $\geq 3$	0.23	1.25 (0.71 to 2.21)	0.61	0.43
Age*	-.023	0.98 (0.95 to 1.01)	2.23	0.14
Diabetes (Reference: no)	.206	1.23 (0.88 to 1.71)	1.46	0.23
Smoking (Reference: no)	0.08	1.08 (0.66 to 1.77)	0.30	0.75
ROM				
Intact	ref	ref	5.48	0.07
<12 hours	-.62	0.54 (0.24 to 1.21)	2.25	0.13
$\geq 12$ hours	.42	1.52 (0.80 to 2.87)	1.64	0.20
Types of C-Section (Reference: elective)	0.20	1.22 (0.78 to 1.92)	0.75	0.39
Length of surgery*	0.003	1.00 (1.00 to 1.01)	1.45	0.23

**Model likelihood  $\chi^2 = 26.16$ ,  $df\ 14$ ,  $p < 0.05$ ; Nagelkerke  $R^2 = 2.9\%$ ; Percentage correctly classified = 91.5%**

**Abbreviations:** ROM=rupture of members; **Note:** Continuous variable\*

**Supplementary table C: Clinical outcomes for intention-to-treat population where missing data on the primary outcome (28 women) is assumed SSI, favouring ci-NPWT<sup>¶1</sup>**

<b>^Clinical Outcomes</b>	<b>All (n = 2035)</b>	<b>ci-NPWT (n =1017)</b>	<b>Standard dressing (n=1018)</b>	<b>Relative risk (95% CI)</b>	<b>p-value<sup>a</sup></b>
All type of SSI	202 (9.9)	84 (8.3)	118 (11.6)	0.71 (0.55 to 0.93)	0.01

*Note:* ¶ ‘Best case’ analysis; Data are n (%); ^ Results for the other outcomes reported in Table 2a are the same, so have not been reported in this table to reduce repetition.

Abbreviation: ci-NPWT, closed incision negative pressure wound therapy; SSI, surgical site infection; CI, confidence interval.

<sup>a</sup>  $\chi^2$  Analyses

<sup>1</sup> For the 28 women missing primary outcome data (12 LTFU; 16 withdrawn) we have assumed these women did have an SSI (favouring ci-NPWT, as it had lower levels of missing data).

**Supplementary table D: Clinical outcomes based on complete case analysis<sup>2</sup>**

Clinical Outcomes	All (n = 2007)	ci-NPWT (n =1008)	Standard dressing (n=999)	Relative risk (95% CI)	p-value <sup>a</sup>
<b>All type of SSI</b>	174 (8.7)	75 (7.4)	99 (9.9)	0.75 (0.56 to 1.00)	0.05
Superficial	163 (93.7)	70 (93.3)	93 (93.9)	0.75 (0.55 to 1.04)	0.72
Deep incision	10 (5.7)	4 (5.3)	6 (6.1)	0.66 (0.19 to 2.33)	0.72
Organ/Space	1 (0.6)	1 (1.3)	0 (0)	..	0.07
<b>Complications</b>	247 (12.3)	123 (12.2)	124 (12.4)	0.98 (0.78 to 1.24)	0.89
Bleeding	30 (1.5)	14 (1.4)	16 (1.6)	0.87 (0.43 to 1.77)	0.72
Dehiscence	211 (10.5)	108 (10.7)	103 (10.3)	1.04 (0.81 to 1.34)	0.77
Haematoma	17 (0.8)	11 (1.1)	6 (0.6)	1.82 (0.68 to 4.89)	0.23
Seroma	53 (2.6)	27 (2.7)	26 (2.6)	1.03 (0.61 to 1.75)	0.92
HLOS (days), median (IQR)	2007 (100)	3 (2.0 to 4.0)	3 (2.0 to 4.0)	..	0.32
Readmissions	36 (1.8)	23 (2.3)	13 (1.3)	1.75 (0.90 to 3.44)	0.10
Pain <sup>b</sup>	32 (1.6)	21 (2.1)	11 (1.1)	1.89 (0.92 to 3.90)	0.08
Reoperations <sup>c</sup>	9 (0.4)	4 (0.4)	5 (0.5)	0.79 (0.21 to 2.94)	0.75

*Note:* Data are n (%) or median (IQR), unless otherwise stated.

Abbreviation: ci-NPWT, closed incision negative pressure wound therapy; SSI, surgical site infection; HLOS, hospital length of stay; IQR, interquartile range; CI, confidence interval.

<sup>a</sup>  $\chi^2$  Analyses, Fisher's Exact test, Mann-Whitney *U* test used.

<sup>b</sup> Pain associated with surgical wound requiring readmission was measured as a binary variable (y/n).

<sup>c</sup> 5 participants had reoperations prior to hospital discharge for wound complications.

<sup>2</sup> For the 28 women missing primary outcome data (12 LTFU; 16 withdrawn), they have been excluded from this analysis.

**Supplementary table E: Clinical outcomes for per-protocol population<sup>3</sup>**

Clinical Outcomes	All (n = 1979)	ci-NPWT (n =996)	Standard dressing (n=983)	Relative risk (95% CI)	p-value <sup>a</sup>
<b>All type of SSI</b>	172 (8.7)	74 (7.4)	98 (10)	0.75 (0.56 to 1.0)	0.05
Superficial	161 (93.6)	69 (93.2)	92 (93.9)	0.74 (0.55 to 1.0)	0.72
Deep incision	10 (5.8)	4 (5.4)	6 (6.1)	0.66 (0.19 to 2.32)	0.72
Organ/Space	1 (0.6)	1 (1.4)	0 (0)	..	0.07
<b>Complications</b>	242 (12.2)	119 (11.9)	123 (12.5)	0.96 (0.75 to 1.21)	0.70
Bleeding	30 (1.5)	14 (1.4)	16 (1.6)	0.86 (0.42 to 1.76)	0.69
Dehiscence	208 (10.5)	105 (10.5)	103 (10.5)	1.01 (0.78 to 1.30)	0.96
Haematoma	17 (0.9)	11 (1.1)	6 (0.6)	1.81 (0.67 to 4.87)	0.23
Seroma	51 (2.6)	26 (2.6)	25 (2.5)	1.03 (0.60 to 1.77)	0.93
HLOS (days), median (IQR)	1979 (100)	3 (2.0 to 4.0)	3 (2.0 to 4.0)	..	0.29
Readmissions	35 (1.8)	22 (2.2)	13 (1.3)	1.67 (0.85 to 3.30)	0.14
Pain <sup>b</sup>	31 (1.6)	20 (2)	11 (1.1)	1.79 (0.86 to 3.73)	0.11
Reoperations <sup>c</sup>	9 (0.5)	4 (0.4)	5 (0.5)	0.79 (0.21 to 2.93)	0.75

Data are n (%) or median (IQR), unless otherwise stated.

Abbreviation: ci-NPWT, closed incision negative pressure wound therapy; SSI, surgical site infection; HLOS, hospital length of stay; IQR, interquartile range; CI, confidence interval.

<sup>a</sup>  $\chi^2$  Analyses, Fisher's Exact test, Mann-Whitney *U* test used.

<sup>b</sup> Pain associated with surgical wound requiring readmission was measured as a binary variable (y/n).

<sup>c</sup> 5 participants had reoperations prior to hospital discharge for wound complications.

<sup>3</sup> The per-protocol population excludes participants (n=56) that were lost to follow up (12 [<1%] participants), not receiving the treatment to which they were originally allocated (28 [1%] participants) and subsequent withdrawal from the study (16 [<1%] participants). 1[%] participant that has withdrawn from the study did not receive the treatment to which she was originally allocated.